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IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

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KENNETH CHRISTISON, *individually and as  
surviving spouse of Annalee Christison,  
deceased, and as personal representative of the  
estate of Annalee Christison, deceased,*

Plaintiff,

v.

BIOGEN IDEC,

ELAN PHARMACEUTICALS, LLC,

Defendants.

MEMORANDUM DECISION

Case No. 2:11-cv-01140-DN-DBP

District Judge David Nuffer

Magistrate Judge Dustin B. Pead

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**I. INTRODUCTION**

This matter was referred to the Court under 28 U.S.C. § 636(b)(1)(A). (Docket No. 117.) On February 23, 2015, Defendants filed a joint motion to exclude Dr. Eugene Major's expert report and to disqualify Dr. Major as an expert on the basis of federal regulations. (Dkt. No. 136.) For the reasons set forth below, the Court **DENIES** Defendants' motion.

**II. BACKGROUND**

Plaintiff alleges that Defendants negligently developed and marketed Tysabri, a multiple sclerosis medication. (*See* Dkt. No. 96 at 14–24.) Plaintiff further alleges that Defendants failed to test Tysabri sufficiently and failed to warn patients who took Tysabri that the medication increased their risk for developing a brain disease called Progressive Multifocal

Leukoencephalopathy (“PML”). (*Id.*) Due to Defendants’ alleged negligence, Plaintiff’s wife, who took Tysabri for multiple sclerosis, developed and died from PML. (*Id.*)

### **III. DEFENDANTS’ MOTION TO STRIKE DR. MAJOR’S REPORT AND EXCLUDE TESTIMONY.**

Defendants argue that Dr. Major should not be allowed to testify because he formerly worked for the National Institute of Health (“NIH”) and, in that capacity, received confidential and sensitive information regarding Defendants. (Dkt. 136.) Defendants cite United States Department of Health and Human Services (“DHHS”) regulations to support their position:

No employee or former employee of the DHHS may provide testimony or produce documents . . . concerning information acquired in the course of performing official duties . . . unless authorized by the Agency head . . . .

*Id.* (quoting 45 C.F.R. § 2.3).

Plaintiff argues that 45 C.F.R. § 2.3 is merely a statement of policy rather than a substantive provision of law and that it does not establish blanket governmental privilege that would bar Dr. Major’s testimony. (Dkt. 139.) Plaintiff further argues that DHHS is the proper entity to enforce the regulations invoked and that, even if DHHS was inclined to intervene, it likely could not strike Dr. Major’s report or completely prohibit him from testifying.

#### **a. Defendants do not cite any authority that requires the Court to strike Dr. Major’s report or preclude him from testifying.**

The regulation cited is not a rule of evidence, nor does it augment the Federal Rules of Civil Procedure. The *Touhy* case, which is often cited as upholding regulations such as 45 C.F.R. § 2.3,<sup>1</sup> is substantially narrower than Defendants suggest. *Touhy* dealt only with a discrete issue: whether the head of an executive agency can prohibit an employee from divulging internal agency records even when those documents are the subject of a valid subpoena. *U.S. ex rel.*

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<sup>1</sup> Such regulations are commonly referred to as *Touhy* regulations.

*Touhy v. Ragen*, 340 U.S. 462, 468 (1951). The Supreme Court held that the agency could prohibit such disclosure as a matter of internal policy because “the usefulness, indeed the necessity, of centralizing determination as to whether subpoenas duces tecum will be willingly obeyed or challenged is obvious.” *Id.* The *Touhy* case involved a current—not former—employee and it did not consider exclusion of a witness based on the regulation. Further, the Supreme Court expressly declined to rule on the propriety of the agency withholding the information. Rather than creating a rule of exclusion, *Touhy* merely upheld a regulatory scheme that allows the head of an agency to determine the timing and scope of agency disclosures.

Also, the cited regulation is promulgated pursuant to 5 U.S.C. § 301, which provides:

The head of an Executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public.

5 U.S.C. § 301. The Supreme Court has interpreted this statute as merely a “housekeeping statute,” without substantive effect. *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979) (“Nothing in the legislative history of [§ 301] shows that Congress intended this statute to be a grant of authority to the heads of the executive departments to withhold information from the public or to limit the availability of records to the public.”). Thus, Section 2.3 merely creates an internal system for DHHS to control the flow of information out of its offices. The regulation does not create an evidentiary privilege or augment the Federal Rules of Civil Procedure.

**b. The Court declines to strike the report or exclude Dr. Major’s testimony under Rule 26.**

Although the regulations do not themselves mandate exclusion, the Court has discretion to enter appropriate discovery orders. *See* Fed. R. Civ. P. 26(b)(2). Defendants cite several cases in favor of exclusion, but none of them convince the Court that exclusion is warranted here.

Defendants cite *Boca Raton Community Hospital, Inc. v. Tenet Healthcare Corp.* to demonstrate that former employees can be prohibited from testifying. *See* 2006 U.S. Dist. LEXIS 38560. That case is readily distinguishable. In *Boca Raton*, the United States appeared as amicus and moved for a protective order to exclude a former DHHS employee's declaration and prohibit his deposition. *See id.* at \*2–3. Further, the proposed relief was limited. The United States sought only to prohibit the deposition until such time as the former employing agency made its decision about whether the employee could testify about certain matters. *Id.* at 5.

Here, the United States has not made any attempt to appear in this case. Likewise, the Court has not been made aware an attempt by the United States or NIH to prevent Dr. Major's testimony. While Plaintiff may be taking a risk by utilizing Dr. Major's testimony without authorization (Defendants suggest such authorization is both necessary and lacking), Defendants have not convinced the Court that Plaintiff should be prohibited from taking that risk.

Likewise, Defendants cite *U.S. ex rel. Pogue v. Diabetes Treatment Centers of America*, but it was the United States that sought to prohibit testimony in *Pogue*, not a private litigant. 474 F. Supp. 2d 75, 79 (D.D.C. 2007). Further as the *Pogue* court recognized, "there is no authority indicating that HHS can block *all* testimony by a *former* employee as to that individual's personal opinions and observations, absent the assertion of a specific privilege." *Id.* at 80. Defendants do not cite to discrete pieces of information that Dr. Major received and should not discuss. Instead, they attempt to exclude his testimony altogether by arguing that Dr. Major is indelibly tainted by his past work. Even under the authority on which they rely, Defendants' proposed relief is extreme.

Finally, the policy rationale underlying the regulations is best served through enforcement by the United States, rather than private litigants. The United States can best determine whether

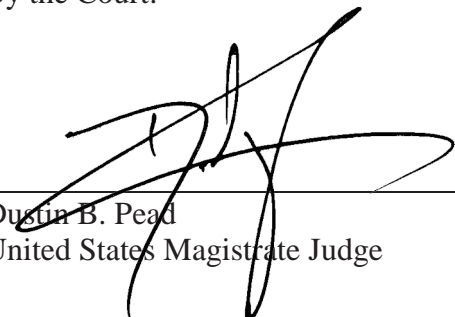
proposed testimony falls within the scope of 45 C.F.R. § 2.3 and when enforcement is necessary to preserve the institutional candor of regulated entities. Private litigants, though well intended, may take these regulations too far, attempting to exclude information to gain a litigation advantage, rather than to serve the public interest. Accordingly, the Court declines to strike the report or prohibit Dr. Major from testifying.

#### **IV. ORDER**

For the reasons analyzed above, the Court **DENIES** Defendants' joint motion to disqualify and to strike. (Dkt. 136.)

Dated this 30<sup>th</sup> day of March, 2015.

By the Court:



Dustin B. Pead  
United States Magistrate Judge